# 510(k) Summary

## Summary of Safety and Effectiveness

**Applicants Name and Address:**

Dräger Medical AG & Co. KG
Moislinger Allee 53-55
23542 Lübeck
Germany

Establishment Registration Number: 9611500

**Contact Person:**

Ullrich Schröder
Director Regulatory and Clinical Affairs

Tel. No.: + 49 (451) 882-3648
Fax No.: + 49 (451) 882-3018

**Applicants US Contact Person**

Ms. Joyce Kilroy
VP Processes, Quality & Regulatory Affairs

Tel. No.: (215) 660-2626
Fax No.: (267) 885-9989

**Date submission was prepared:**

2009-11-11

**Device Name:**

**Trade Name:** VentStar Resuscitaire CEU

Common Name: Positive End Expiratory Pressure Breathing Attachment

**Classification:**
Class II

| Regulation No. | Device | Product Code |
|---|---|---|
| Preferred Code: | | |
| 868.5965 | Positive End Expiratory Pressure Breathing Attachment | BYE |
| For predicates: | | |
| 868. 5965 | Positive End Expiratory Pressure Breathing Attachment | BYE |

**Legally Marketed Device to which Substantial Equivalence is claimed:**

| 510(k) number | Trade name | Company |
|---|---|---|
| K070416 | NeoPeep | Neoforce Group, Inc. |

**Device Description:**

The VentStar Resuscitaire CEU with PEEP valve is indicated as accessory to add positive end expiratory pressure breathing capability. The valve is designed into the T-Piece of the breathing circuit with a standard fitting for face mask, laryngeal mask or endotracheal tube.

**Intended Use:**

The VentStar Resuscitaire CEU with PEEP valve is indicated as an accessory to add positive end expiratory pressure breathing capability. The valve is designed into the breathing circuit T-Piece with a standard fitting for face mask, laryngeal mask or endotracheal tube.

The VentStar Resuscitaire CEU is a disposable breathing circuit for the transmission of breathing gases from a breathing gas source (Resuscitation Module) to the newborn patient in labor and delivery environments. It is suitable for newborn patients from birth to 1 month of age (maximum body weight of 10 kg (22 lb)). It is intended exclusively for use in combination with the Resuscitaire Radiant Warmer.

**Substantial Equivalence:**

The intended use and indications for use of VentStar Resuscitaire CEU are similar to the referenced predicate device, the NeoPeep Neonatal Resuscitation Circuit.

Both devices contain a PEEP valve and connect directly to standard endotracheal tubing.

A comparison of the data shows the same values for the key performance parameters.

| | VentStar Resuscitaire CEU | NeoPeep |
|---|---|---|
| Connector | 15 mm | 15mm |
| Material | Latex Free, DEHP Free | Latex Free, DEHP Free |
| Flow Rate | 5 to 15 lpm | 5 to 15 lpm |
| Peep | Adjustable and Dependant on Flow | Adjustable and Dependant on Flow |
| Maintenance/Cleaning | Disposable | Disposable |

Neither the VentStar Resuscitaire CEU nor the predicate contain software or electrical components.

Biocompatibility testing was performed per ISO 10993 - Biological Evaluation of Medical Devices Parts 1, 5 & 12.

Performance assessment of the VentStar Resuscitaire CEU included non-clinical bench testing per ISO 5356 Anesthetic and Respiratory Equipment – Conical Connectors Part 1, ISO 5367 Breathing tubes intended for use with anesthetic apparatus and ventilators, and system compatibility testing.

In summary Dräger Medical AG & Co. KG has demonstrated that the proposed device is safe and effective and is substantially equivalent, based on intended use, design, operational and technological characteristics, and principles of operation, to the NeoPeep Neonatal Resuscitation Circuit

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 7 2010

Draeger Medical AG & Company KG
C/O Ms. Joyce Kilroy
Draeger Medical System, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K092029
Trade/Device Name: VentStar Resuscitaire CEU, Model MP00310
Regulation Number: 21 CFR 868.5965
Regulation Name: Positive and Expiratory Pressure Breathing Attachment
Regulatory Class: II
Product Code: BYE
Dated: August 2, 2010
Received: August 3, 2010

Dear Ms. Kilroy:

This letter corrects our substantially equivalent letter of August 25, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K092029

Device Name: VentStar Resuscitaire CEU

Indications for Use:

The VentStar Resuscitaire CEU with PEEP valve is indicated as an accessory to add positive end expiratory pressure breathing capability. The valve is designed into the breathing circuit T-Piece with a standard fitting for face mask, laryngeal mask or endotracheal tube.

The VentStar Resuscitaire CEU is a disposable breathing circuit for the transmission of breathing gases from a breathing gas source (Resuscitation Module) to the newborn patient in labor and delivery environments. It is suitable for newborn patients from birth to 1 month of age (maximum body weight of 10 kg (22 lb)). It is intended exclusively for use in combination with the Resuscitaire Radiant Warmer.

The VentStar Resuscitaire CEU is a prescription device.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices



510(k) Number: K092029